PERSPECTIVE

Translating Ideals For Health Information Technology Into Practice

A three-tier architecture to help standards for health information technology gain acceptance and widespread use.

by David J. Brailer

ABSTRACT: Standards for communication, content, function, and clinical knowledge are essential for electronic health records and e-prescribing, as well as other health information technologies. The current process for standard setting is competitive and voluntary, and it does not ensure that accepted standards will be incorporated into health information products. A three-tier architecture of development (research and validation), authorization (approval and dissemination), and certification (product evaluation) will make standards a core feature of future health information technology. Patient safety, health information technology uptake, and portability of data would all be enhanced by an orderly standard-diffusion process.

THE PAPER BY Douglas Bell and colleagues prioritizes and rates specific features of electronic prescribing tools.[1] This work joins a growing number of efforts to define the requirements for the information tools that will automate and transform health care into a safer, more effective, and highly efficient industry. These efforts include data content and communications standards for electronic communication, such as those announced by Health and Human Services (HHS) Secretary Tommy G. Thompson in 2003 and further updated by a variety of standard-setting bodies and the federal Consolidated Health Informatics (CHI) initiative. Also updated were clinical vocabulary and terminology standards (such as the Systematized Nomenclature of Medicine, or SNOMED), electronic health record feature and function standards (for example, the second Health Level 7, or HL7, balloting that was recently completed), portability standards for moving patient care data between systems (such as the Continuity of Care Record, or CCR), standards for patient and physician identity, and clinical guidelines and rules.

The movement toward standardizing systems is positive and will set a foundation for long-term growth in clinical automation and health information exchange. However, the growing chorus of standards and the array of quasi-standard-setting groups demonstrate that what we lack are not standards in theory but standards in reality. Standard-setting groups, even while collaborating, often develop conflicting standards for the same topic. While organizations such as the American National Standards Institute (ANSI) Healthcare Information Standards Board are chartered to harmonize standards, there has been limited

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success in organizing current standards into a cohesive whole, let alone looking forward to future standards such as those described by Bell and his colleagues.

The Status Quo

Vendors, hospitals, physicians, health plans, and other entities are confused by conflicting standards. As a result, they are cautious about investing time and resources in standards or incorporating them into their software tools. This harms the effort to make standards real and out-of-the-box features of information tools, and it hampers the advances in quality and efficiency that could arise from widespread use of these standards. Would the Internet have come into being, or the business transformation it created have occurred, if multiple parties had set standards? Without the authorizing control of ICANN (Internet Corporation for Assigned Names and Numbers, the global Internet convention-setting organization), Web pages wouldn't appear, e-mail wouldn't arrive, and files wouldn't transfer. Interoperability would have been a nice idea, but not much of a reality.

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Even if the next decade of health information standard setting were disciplined by having a unified mechanism to amalgamate standards into one set, standards still may not come into widespread use. We rely on voluntary behavior to translate standards that are adopted (read in, approved as ready for use) into standards that are adopted (that is, being used). There are some exceptions, such as federal efforts to include standards in federal procurement through eGov, CHI, and the pending adoption and regulation of electronic prescribing standards under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Otherwise, the diffusion of standards and their incorporation into real software is laissez-faire. The first-mover disadvantages that accrue to early adopters of standards suggest that voluntary adoption will take a very long time and may not succeed at all.

One way to bring standards into use is to mandate them into law. Legislated standards do synchronize adoption, but, as experience with the Health Insurance Portability and Accountability Act (HIPAA) of 1998 has shown, they also bring unintended consequences that are of great concern. The future regulation of e-prescribing standards can be informed by this experience and by the testing and evaluation of standards prior to regulation.

There are certainly vehicles for the diffusion of standards that are not as passive as voluntary adoption or as mandatory as legislation. Many medical devices have to meet a variety of standards—some required, others voluntary—to be marketed in health care or to be reimbursed by Medicare or other payers. Consider magnetic resonance imaging (MRI) machines, ultrasound machines, Picture Archival and Communications Systems (PACS), patient monitors, electrocardiogram machines, and many other standardized clinical tools that are essentially information tools with specialized clinical functions. These products are subject to a variety of inspections, certifications, or reviews to ensure that they meet minimal standards. Over time, this process has taken on an important role in improving patient safety, guarding payers and providers from frivolous expenditures and mitigating investment risk to developers of new technology.

Why should electronic health records be treated differently from other diagnostic and therapeutic tools based on information technology? Like MRIs, for example, electronic health records collect a variety of data, summarize data with algorithms, store and communicate data, and present data in a meaningful way to clinicians. Both MRIs and electronic

health records provide information that supplements clinicians' diagnostic decision making, refines choice of treatments, and supplements monitoring of patients' progress over time. Neither is useful or reliable without a physician's guidance and oversight. Both can harm patients if overused, underused, or used improperly, or if they do not perform as promised, whether through malfunction, poor maintenance, or design defect.

Three Tiers Of Standards

I suggest that private-sector standards organizations adopt a three-tier architecture that will accelerate the adoption of health information standards and make interoperability a true foundation for the industry. The tiers would be as follows.

■ **Tier 1: development.** The process would be much like it is today: Expert panels and consensus groups determine the detailed attributes of a given standard, test the standard, and advocate for it. Many organizations may compete on standards, and some may collaborate. A variety of overlapping organizations would engage in standard development.

■ **Tier 2: authorization.** One single private organization or commission would be vested with the authority by standard-development organizations to determine which standards are to be adopted, when they should be put into use, what the schedule for future standards should be, and what gaps exist in existing standards. This organization essentially ratifies and coordinates the flow of standards into the market and provides a managed mechanism for orderly progress over time.

■ **Tier 3: certification.** One or more private organizations would be chartered to perform inspections of specific products that are being sold to determine their compliance with authorized standards. Vendors or buyers could request certification for products at any time during a product's life cycle. Certification should be voluntary, although payers may link pay-for-performance or grant other privileges to certified products. Information about certified products should be publicly available.

■ **Implementing the architecture.** The authorization and certification organizations would be best created by voluntary consensus of current standard-development bodies. To succeed, these organizations require broad governance and the buy-in of multiple stakeholders, including consumers, physicians, hospitals, and health plans. The authorizing organization could also perform certification, although this would require mechanisms to ensure that the struggle for economic power created through certification does not harm the credibility or effectiveness of the authorization process.

Such a standard-diffusion architecture would increase the confidence of buyers and sellers of information tools that the correct product is being developed and delivered. It would accelerate the recognition of the profound relevance of standards to people who don't discuss standards for a living. Most importantly, such an approach would foster a thriving health information services industry that can exceed customers' expectations, innovate and invest in new research, and attract private capital to leverage public funds. It would provide a mechanism for new standards, such as those published here about electronic prescribing, to have a clear path from concept to use.

The opinions expressed in this paper are solely those of the author and not of any organization with which he is affiliated.

NOTE

1. D.S. Bell et al., "Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process," *Health Affairs,* 25 May 2004, content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.305 (25 May 2004).